REMARKS

Applicant wishes to thank Examiner Stuart Snyder and Supervisor Bruce Campell for the courtesy extended to Nancy Vensko, attorney of record, on 4 August 2006. The Interview Summary Form PTOL-413 summarizes the discussion held at the personal interview. The present response to the outstanding Office Action includes the substance of the Examiner Interview.

A. Disposition of Claims

Claims 15-17, 19, and 23-25 are pending in this application. The enablement rejection is appreciated as being withdrawn in view of the restriction of the claims, because the Patent Office agrees that the PEGylation embodiment is enabled. Reexamination and reconsideration of the application, as amended, are respectfully requested.

B. Compliance with 35 USC 103(a)

The issue is whether the claims are in compliance with 35 U.S.C. §103(a) or unpatentable as being obvious over **Smith et al., Journal of General Microbiology 128: 307 (1982) in view of Nucci et al., Advanced Drug Delivery Reviews 6: 133 (1991)**. The rule according to MPEP 2143 is that to establish a prima facie case of obviousness: First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations.

The prior art references do not teach or suggest all the claim limitations. Smith et al. describes a problem associated with use of bacteriophage in phage therapy. Nucci et al. describes use of PEG for modification of proteins. In contrast, the claims make use of PEG for modification of bacteriophage. The element of PEGylated bacteriophage is missing from the prior art references.

There is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. There is nothing in the prior art references to teach the substitution of bacteriophage for proteins. According to Nucci et al., on p. 137, last paragraph, PEG decreases the activity of the protein. Bacteriophage may be composed of proteins, and proteins

may suffer minimal loss of activity. But proteins are not live viruses whose function of infectivity must be preserved to be effective in phage therapy.

Nucci et al. actually teaches away from use of PEG for modification of bacteriophage. The Patent Office agrees that Hepatitis B vaccine is mentioned in Table 1 of Nucci et al. Use of PEG for vaccines (their functionalization) is also described on page 144, 3rd full paragraph. The goal of vaccines is to retain immunogenicity to stimulate a host immune response. By comparison, the purpose of PEGylating bacteriophage would be to reduce immunogenicity to escape the host defense system. Thus, Nucci et al. actually teaches away because the disclosure would discourage the use of PEG for modification of bacteriophage when the objective of PEGylating bacteriophage is to reduce immunogenicity but the result of PEGylating bacteriophage might be to retain immunogenicity.

There was no reasonable expectation of success as described in the attached Declaration of Dr. Merril.

For these reasons, a prima facie case of obviousness is successfully attacked or rebutted. The conclusion is that the claims are non-obvious over the references. Thus, the claims are in compliance with 35 U.S.C. §103(a).

CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

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Dated: 9/1/06

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